PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 17370-006WO1	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2005/035951	International filing date *(day/month/year)* 05 October 2005 (05.10.2005)	Priority date *(day/month/year)* 05 October 2004 (05.10.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant TOMOPHASE CORPORATION		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 24 February 2009 (24.02.2009)
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference 17370-006WO1	Date of mailing (*day/month/year*) 29 AUG 2008 **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US05/35951	05 October 2005 (05.10.2005)	05 October 2004 (05.10.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC: **A61B 5/00**(2006.01),**6/00**(2006.01)
USPC: 600/310,316,322,365,473,476

Applicant

TOMOPHASE CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn. ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	17 June 2008 (17.06.2008)	Brian Casler Telephone No. 5712723700

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/35951

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/35951

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-9,11-14 and 18-20	YES
	Claims 10, 15-17	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-20	NO
Industrial applicability (IA)	Claims 1-20	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 10 and 15-17 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 6,725,073 B1 to Motamedi (Motamedi).

In Reference to Claim 10

Motamedi teaches the use of an optical coherence tomography system for measuring analyte (i.e. glucose concentration). The system consists of -

A device for optically measuring a sample (see figure 10), comprising:

a) a plurality of light sources emitting light at different wavelength bands centered at different wavelengths (see column 7, lines 57-64 and claim 4);

b) a single waveguide to receive and guide the light at the different wavelength bands in a first propagation mode (see 10 and claim 44);

c) a probe head coupled to the waveguide to receive the light from the waveguide and to reflect a first portion of the light back to the waveguide in the first propagation mode and direct a second portion of the light to a sample (see column 2, lines 49-59), the probe head collecting reflection of the second portion from the sample and exporting to the waveguide the reflection as a reflected second portion in a second propagation mode different from the first propagation mode (see claim 38 and column 3, lines 3-12);

d) an optical differential delay unit to produce and control a relative delay between the reflected first portion and the reflected second portion received from the single waveguide in response to a control signal (see figure 10 and column 6, lines 3-11);

e) a detection module to receive the reflected first portion and the reflected second portion in the waveguide and to extract information of the sample carried by the reflected second portion (see figure 10); and

Supplemental Box
In case **the space in any of the preceding boxes is not sufficient**.

f) a control unit, which produces the control signal to the optical differential delay unit, to set the relative delay at two different bias values to select a layer of material inside the sample to measure an optical absorption of the selected layer at each and every wavelength from the different light sources (see column 9, lines 1-7).

In Reference to Claims 15-17

Motamedi has been shown to teach all of the limitations of claim 10. In addition Motamedi further teaches:

Re claim 15:

The device as in claim 10, further comprising an optical element to receive the light at different wavelength bands from the light sources and to combine the received light into the single waveguide.(see figure 10, and column 7, lines 57-64).

Re claim 16:

The device as in claim 10, wherein the light sources are fixed in their emitting wavelengths(see column 7, lines 54-56).

Re claim 17:

The device as in claim 10, further comprising a mechanism to move a position of the second portion of the light relative to the sample to measure different locations on the sample (see column 3, lines 6-8 and 34-36).

Claims 1-9, 11-13 and 18-20 lack an inventive step under PCT Article 33(3) as being obvious over US Patent No. 6,725,073 B1 to Motamedi (Motamedi)
in view of US Patent No. 5,803,909 to Maki (Maki).

In Reference to Claims 1

Motamedi teaches.
A method, comprising.

a) combining and guiding optical radiation from a plurality of light sources, each emitting at wavelengths within a spectral band different from others, towards a sample through a common optical waveguide (see figure 10, abstract, claims and 4 and column 7, lines 57-64);

b) reflecting a first portion of the combined radiation away from the sample at its vicinity while directing a second portion of the combined radiation to reach the sample (see figures 10, and column 3, lines 5-9);

c) collecting and guiding at least part of the reflected first portion and at least part of a reflected second portion from the sample towards a detection module through the common optical waveguide (see figures 10, and columns 2, lines 49-57 and 3, lines 9-10);

However, Motamedi does not **explicitly** disclose a method comprising:

d) separating the light into a plurality of spectral bands corresponding to emitting spectral bands of the light sources; and directing light radiation of the separated spectral bands to a plurality of light detectors, respectively.

Maki, in the same field of endeavor, discloses a multispectral optical system for imaging and measuring various metabolic parameters within the body (see figure 2 and abstract). Maki cites the implementation of a plurality of multispectral light irradiation and receiving units in order to measure the "interior of a living body with ease without adversely affecting the living body' (see column 1, lines 6-14)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of "separating the light into a plurality of spectral bands corresponding to emitting spectral bands of the light sources; and directing light radiation of the separated spectral bands to a plurality of light detectors, respectively" of Maki in the method of Motamedi in order to facilitate the measurement and imaging of in vivo information using light as explicitly taught by Maki (see column 1, lines 9-11).

In Reference to Claim 2

Motamedi in view of Maki has been shown to teach all of the limitations of claim 1. Motamedi further teaches:

Supplemental Box
In case **the space in any of the preceding boxes is not sufficient.**

"The method as in claim1, further comprising controlling the reflected first portion to propagate inside the common waveguide in a first propagation mode and the reflected second portion to propagate inside the common waveguide in a second propagation mode that is different from the first propagation mode (see figure 10 and claim7).

Therefore, Motamedi in view of Maki teaches all claim 2 limitations.

In Reference to Claim 3

Motamedi in view of Maki has been shown to teach all of the limitations of claim 2. Motamedi further teaches:

"The method as in claim 2, wherein the first propagation mode is a first polarization mode of the common waveguide and the second propagation mode is the second polarization mode that is perpendicular to the first polarization mode of the common waveguide (see figure 10 and claim7).

Therefore, Motamedi in view of Maki teaches all claim 3 limitations.

In Reference to Claim 4

Motamedi in view of Maki has been shown to teach all of the limitations of claim 1. Motamedi in view of Maki further teaches:

" The method as in claim 1, further comprising using broadband light emitters as the light sources, wherein each emitter has a broad spectrum centered at a wavelength different from wavelengths of other emitters" (see Maki column 4, lines 7-14 and column 8, lines 1-10).

Therefore, Motamedi in view of Maki teaches all claim 4 limitations.

In Reference to Claim 5

Motamedi in view of Maki has been shown to teach all of the limitations of claim 1. Motamedi in view of Maki further teaches:

"The method as in claim 1, further comprising using tunable laser sources as the light sources, wherein each tunable laser source emits coherent light at a wavelength tunable through a spectral band that is different from spectral bands of other tunable laser sources" (see Maki column 8, lines 8-15).

Therefore, Motamedi in view of Maki teaches all claim 5 limitations.

In Reference to Claim 6

Motamedi in view of Maki has been shown to teach all of the limitations of claim 1. Motamedi in view of Maki further teaches:

"The method as in claim 1, further comprising: producing a delay between the reflected first and second portions; and modulating the relative delay between the reflected first portion and the reflected second portion to measure a variation in power of light at each light detector" (see Motamedi column 6, lines 5-11 and claim 44).

Therefore, Motamedi in view of Maki teaches all claim 6 limitations.

In Reference to Claim 7

Motamedi in view of Maki has been shown to teach all of the limitations of claim 1. Motamedi in view of Maki further teaches:

"The method as in claim1, further comprising: adjusting a relative delay between the reflected first portion and the reflected second portion received from the single waveguide at two different delay values to select a layer of material inside the sample to measure an optical absorption of the selected layer at each and every wavelength from the different light sources" (see Motamedi claim 44).

Therefore, Motamedi in view of Maki teaches all claim 7 limitations.

In Reference to Claim 8

Motamedi in view of Maki has been shown to teach all of the limitations of claim 1. Motamedi in view of Maki further teaches:

Supplemental Box
In case **the space in any of the preceding boxes is not sufficient**.

" The method as in claim 1, further comprising simultaneously directing light from the different light sources through the single, common waveguide to the sample" (see Motamedi figure 10 and column 7, lines 57-64).

Therefore, Motamedi in view of Maki teaches all claim 8 limitations.

In Reference to Claim 9

Motamedi in view of Maki has been shown to teach all of the limitations of claim 1. Motamedi in view of Maki further teaches:

"The method as in claim 1, further comprising sequentially directing light from the different light sources, one at a time, through the single, common waveguide to the sample" (see Maki columns 4, lines7-16 and 16, lines 3-15).

Therefore, Motamedi *in view of Maki teaches all claim 9 limitations.*

In Reference to Claim 11

Motamedi has been shown to teach all of the limitations of claim 10. However, Motamedi fails to explicitly disclose:

"The device as in claim 10, wherein the detection module comprises:
an optical device to separate light at different wavelength bands into different beams; and a plurality of optical detectors to respectively receive and detector the different beams".

Maki's implementation of a multispectral in vivo optical sensing imaging and measurement device with multiple light sources and detectors has already been discussed (see rejection for claim 1, limitation d; see also Maki figure 2 and column 8, lines 1-30). Once again, Maki asserts that the novelty of his invention is that it enables measurement of the "interior of a living body with ease without adversely affecting the living body' (see column 1, lines 6-14).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step "wherein the detection module comprises:
an optical device to separate light at different wavelength bands into different beams; and a plurality of optical detectors to respectively receive and detector the different beams" of Maki in the method of Motamedi in order to facilitate the measurement and imaging of in vivo information using light as explicitly taught by Maki (see column 1, lines 9-11).

In Reference to Claim 12

Motamedi has been shown to teach all of the limitations of claim 10. Motamedi further teaches:

The device as in claim 10, wherein the detection module comprises:

a) an optical device to convert a part of received light in the first propagation mode and a part of received light in the second propagation mode into light in a third
propagation mode that propagates along a first optical path and to convert remaining portions of the received light in the first and the second propagation modes into light in a fourth propagation mode that propagates along a second, different optical path (see figure 10, abstract and columns 2, lines 55-67);

b) a first optical element in the first optical path to separate light at different wavelength bands into a first set of different beams (see figure 10 and column 3, lines 3-11);

d) a second optical element in the second optical path to separate light at different wavelength bands into a second set of different beams(see figure 10 and column 3, lines 3-11);

However, Motamedi fails to explicitly teach the claim 10 device limitations below, but Maki does:

c) a plurality of first light detectors to respectively receive and **detect** the first set of different beams from the first optical element (see figure 2, reference marks 8a-8c, and column 8, lines 1-30);

e) a plurality of second light detectors to respectively receive and detector the second set of different beams from the second optical element (see figure 2, reference marks 8d-8f, and column 8, lines 1-30);

Maki cites reducing the measurement time and thereby lessening the test burden on a patient and improving overall system operating efficiency (see column 2, lines 44-48) as key benefits to this approach.

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step "wherein the detection module comprises:
a plurality of first and second light detectors" of Maki in the method of Motamedi in order to facilitate the time to obtain a measurement and improve system efficiency as explicitly taught by Maki.

In Reference to Claim 13

Motamedi has been shown to teach all of the limitations of claim 11. Motamedi further teaches using an interferometer to effect the necessary signal conditioning(interference) needed between reference and measurement signals in order to image and measure the sample of interest. It is well known in the art that gratings offer an alternative to accomplish similar ends with regard to signal interference. Therefore, barring unexpected results, gratings would not offer any patentable distinction over interferometers and would be solely used as a matter of design choice.

Therefore, Motamedi in view of Maki teaches all claim 13 limitations.

In Reference to Claims 18-20

Claims 18-20 and corresponding device claims 10-12 differ only in the specification of the type of light source. In the case of claims 18-20, the light source is a plurality of tunable laser sources.

Maki further discloses that the light source may be from a "plurality of laser sources" as well (see column 16, lines 8-15).

Claim 14 lacks an inventive step under PCT Article 33(3) as being obvious over US Patent No. 6,725,073 B1 to Motamedi (Motamedi) in view of US Patent No. 6,377,840 B1 to Gritsenko (Gritsenko).